



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
CARIBBEAN ENVIRONMENTAL PROTECTION DIVISION
CITY VIEW PLAZA, SUITE 7000
#48 165 RD. KM 1.2
GUAYNABO, PR 00968-8069

CERTIFIED MAIL /RETURN RECEIPT REQUESTED
Article Number: 7011 0470 0000 5042 2043

MAR 24 2017

Mr. Alvin E. Crespo, Director
Environmental Health and Safety
Bristol-Myers Squibb Manufacturing Company
Humacao Operations
P.O. Box 609
Humacao, Puerto Rico, 00792-1255

Re: Proposed Contained-In Determination Criteria for the Bristol-Myers Squibb Manufacturing Company, Humacao, Puerto Rico
EPA ID Number: PRD 090021056

Dear Mr. Crespo:

The United States Environmental Protection Agency-Region 2 (EPA) and the Puerto Rico Environmental Quality Board (PREQB) have evaluated your request, dated September 7, 2016, to apply the RCRA contained-in policy to contaminated environmental media subject to the active remediation at the Bristol-Myers Squibb Manufacturing Company's (BMSMC's), facility in Humacao, Puerto Rico. As you indicated, the environmental media containing hazardous waste are subject to all applicable RCRA hazardous waste requirements at the point of generation. The letter sets forth the criteria BMSMC would like to employ to determine whether contaminated environmental media, specifically soil and groundwater, generated at the facility contain hazardous waste. Attached please find the PREQB's and the EPA's comments on the criteria proposed in your letter.

Please provide your response to all of our comments within 45 days of receipt of this letter. If you have any questions regarding this correspondence, please contact Socorro Martinez of my staff at (787) 977-5886 or via email at martinez.socorro@epa.gov.

Sincerely,

Carmen R. Guerrero Pérez
Director
Caribbean Environmental Protection Division

cc: Manuel O. Claudio Rodriguez, Manager,
Land Pollution Control Program, PREQB

Enclosure

EPA's General Comments

1. BMSMC's letter does not mention land disposal restrictions (LDR) in the letter. Land disposal restrictions apply to environmental media that contain hazardous waste, and in some instances will continue to apply even after it has been determined that media no longer contain hazardous waste. If a LDR is applicable, then the proposed contain-in criteria may need to be modified accordingly.
2. BMSMC's letter does not address all of the constituents of concern (COCs) for the BMSMC Humacao facility. BMSMC should document how it established the list of constituents set forth in its table labeled "EPA Health-Based Criteria for the RCRA Contained-In Evaluation," and indicate why known COCs at the facility were eliminated.

EPA's Comments on Proposed Criteria and Table

3. BMSMC proposes using the generic EPA Regional Removal Management Levels for Chemicals (RMLs) for residential tap water and industrial soils. Please, noted that the generic RMLs correspond to risk levels of approximately 10^{-4} and/or a Hazard Quotient of up to 3 for long-term exposure to **individual** chemicals at a site. To be conservative, BMSMC should use the RMLs for residential soils rather than the RMLs for industrial soils for the Contained-In determination.
4. The Benzene, Methylene Chloride, Tetrachloroethylene RMLs for residential tap water (46 parts per billion (ppb), 320 ppb, 120 ppb respectively) are least an order of magnitude higher than the corresponding maximum contaminant level (all 5 ppb). BMSMC shall use the EPA maximum contaminant levels of 5 ppb.
5. BMSMC is proposing to use the RCRA toxicity criteria even though the RMLs for residential are lower. BMSMC shall use the RMLs for residential soils.
6. The Benzyl Chloride RML for residential tap water is 5.9 ppb and not 6 ppb.
7. The Tetrahydrofuran RML for industrial soils is 280,000 mg/kg, but the EPA Health-Based Criteria for RCRA Contained-In Evaluation Table lists 105,000 mg/kg for Tetrahydrofuran. This latter number should be used.
8. EPA Health-Based Criteria for RCRA Contained-In Evaluation Table categorized constituents into Potential Carcinogens (Oral Exposure) or Non-Carcinogens (Oral Exposure). These categories are misleading because some of the RMLs are based on combined pathways or other RMLs are based on carcinogenic target risk for the groundwater but non-carcinogenic hazard index for soils. These categories should therefore be removed from this table.

PREQB Comments

9. It is recommended to characterize the waste as per 40 CFR Part 261.
10. The letter indicates that the proposed action does not considered the treatment and disposal end points, only management as part of the corrective action activities. Please provide how the wastes will be managed during the project implementation. The EPA's guidance EPA530-F-98-026 Management of Remediation Waste Under RCRA recommends that even when contaminated media has been treated

and determination that it no longer contains hazardous wastes, the media could still be subject to Land Disposal Restrictions.

11. The letter does not include any sampling description to ensure that a characteristic sample will be taken. The frequency of sampling should also be provided.